FEB 2 6 2009

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510(k) Summary

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92.

Date:	January 14, 2009
Submitter's name:	Lerner Medical Devices, Inc.
Submitter's Address:	1545 Sawtelle Ave. Suite 36 Los Angeles, CA 90025
Submitter's Telephone:	(310) 914 0091
Submitter's Fax:	(310) 914 0095
Contact Person:	Zafirios F. Gourgouliatos, Ph.D., Chief Science Officer Management Representative
Device Trade Name:	LH-75T Phototherapy System
Device Common Name:	Targeted UVB Phototherapy System
Device Classification Name:	Ultraviolet lamp for dermatologic / skin disorders
Regulation Number:	878.4630
Product Code:	FTC
Classification:	Device Class II
Establishment Reg. Number:	3006793564
List of Predicate Devices:	TheraLight, Inc. UV1 20-2 UVA / UVB Phototherapy System K022165, K024020, Lerner Medical Devices, Inc. Levia Phototherapy System K040062 Daavlin Distributing Co. Dermapal with Digital Timer K073587

Device Description:

The LH-75T Phototherapy System is an ultraviolet Light Source and energy delivery system. The System emits UV-B (290-320 nm) light for use in phototherapy and allows delivery of controlled doses.

The LH-75T consists of a Console that contains the electronics and a Handpiece that contains the lamp and the ballast. The console and handpiece are connected with an electrical cable. A Spot Treatment Attachment (LP-3) and a Fiber-optic Brush Attachment (LB-10) are connected to the handpiece for selective treatment of skin lesions without exposure of adjacent, healthy tissues. The desired dose is selected using controls on the panel of the console and activated with either a switch on the panel or foot-switch. The system is powered by a common household AC outlet. Protective eyewear is supplied with the system.

Indications for Use:

The LH-75T Phototherapy System is intended for use, by or under the direction of a physician, in UVB phototherapy for the treatment of psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis and leucoderma.

The LH-75T Phototherapy System is intended for use on all skin types (I -VI).

Substantial Equivalence:

The LH-75T Phototherapy System emits UVB light within the spectral band of 290 -320 nm, similar to that of all the predicate devices. This light has been shown to be safe and effective in the treatment of scalp psoriasis. The difference between the LH-75T Phototherapy System and the predicate devices is the configuration of the hardware.

The delivery components (Spot Treatment Attachment LP-3, Fiber-optic Brush Attachment LB-10) and control electronics are identical to those of the Levia Phototherapy System (Lerner Medical Devices, Inc., K040062).

The lamp is situated the Handpiece and is connected to the console with an electrical cable in a manner similar to the Dermapal with Digital Timer predicate device. (Daavlin Distributing Co., K073587).

The LH-75T Phototherapy System has a Power Meter embodied in the console to facilitate calibration, in a manner similar to the UV1 20-2 UVA / UVB Phototherapy System (TheraLight, Inc., K022165, and K024020). The Power Meter is used to indicate output of the LH-75T for operator convenience. The meter is similar to the meter of the Levia Phototherapy System.

Lerner Medical Devices, Inc. believes that these similarities provide added convenience to the user and do not raise new questions about safety or effectiveness.

Performance Data:

Performance data have been submitted as part of the 510(k) application to confirm that the spectral output of the LH-75T Phototherapy System is between 290 and 320 nm, which is similar to spectra emitted by predicate devices. Other performance data included in the application show that the technological specifications are similar to those of the predicate devices.

Conclusion:

On the basis of the information provided in this summary, Lerner Medical Devices, Inc. believes the LH-75T Phototherapy System is substantially equivalent to legally commercialized predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Lerner Medical Devices, Inc.
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1545 Sawtelle Boulevard, Suite 36
Los Angeles, California 90025

FEB 2 6 2009

Re: K090097
Trade/Device Name: LH-75T Phototherapy System
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet lamp for dermatologic disorders
Regulatory Class: II
Product Code: FTC
Dated: January 14, 2009
Received: January 15, 2009

Dear Dr. Gourgouliatos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

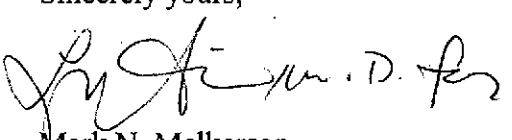
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K090097

Device Name: LH-75T Phototherapy System

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Prescription Use ___X___ OR Over-the-Counter Use _____
(per 21 CFR 801.109)

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for mkn

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090097